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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,403	11/10/2006	Vincenzo Re	PB60550	2439

20462 7590 04/17/2008

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
HOLLOMAN, NANNETTE	
ART UNIT	**PAPER NUMBER**
4131	

NOTIFICATION DATE	DELIVERY MODE
04/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/576,403	RE ET AL.	
	Examiner	Art Unit	
	NANNETTE HOLLOMAN	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8-10,12-14 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-10,12-14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20 Apr 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 8-10, 12-14 and 16 are pending and are the subject of this Office Action. This is the first Action on the merits of the claims.

The Preliminary Amendment filed on April 20, 2006 cancelling claim 15 and amending claims 4, 5, 8, 12-14 and 16 has been received and entered.

Applicant's election without traverse of Group I (claims 1, 8-10, and 12-13) and request of rejoinder of Groups IV and V (claims 14 and 16) is acknowledged. Rejoinder of Groups IV and V (claims 14 and 16) is accepted. Applicant's election of species is also acknowledged, but species election was not required in said restriction.

Specification

The use of the trademark GELUCIRE® 50/13, 44/14, 50/02 and PRECIROL® ATO 5 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “certain complications thereof” renders the claim indefinite.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of diabetes mellitus, does not reasonably provide enablement for treatment and prophylaxis of the diseases broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. ***.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands,* 8 USPQ2d 1400 and *Ex parte Forman,* 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) The quantity of experimentation needed. The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple

factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The instant claim recites “prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof, osteoporosis, Alzheimer’s disease, psoriasis, asthma and metabolic syndrome”. While the compound is enabled for the treatment of diabetes mellitus, applicant provides no competent evidence that the claimed dosage compound can have "prophylaxis" effects on osteoporosis, Alzheimer’s disease, psoriasis, asthma or metabolic syndrome. Metabolic syndrome is defined by the Mayo Clinic as having several disorders related to your metabolism at the same time, to include elevated blood pressure and elevated triglycerides (MayoClinic.com, Metabolic syndrome). There is no evidence that the claimed dosage composition can prevent the disorder. National Institutes of Health discloses there is no known prevention for asthma (National Heart Lung and Blood Institute, NIH, Asthma). “To prevent” actually means *to anticipate or counter in advance, to keep from happening etc. (*as per Websters II Dictionary) and therefore it is nor understood how one skilled in the art can reasonable extablish the basis and the type of subject to which the instant dosage form can be administered in order to have a "prophylaxis" effect.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”' etc. have been demonstrated to be sufficiently lacking in the use of the invention. One having ordinary sill in the art would have to undergo and undue amount of experimentation to use the invention for “prophylaxis” as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8-10, 12-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (U.S. Patent No. 6294192 B1) and Hindley et al (U.S. Patent No. 6288095 B1).

Patel et al. teaches a capsule for oral administration containing a composition of a hydrophobic therapeutic agent, and a carrier of at least one hydrophilic surfactant and at least one hydrophobic surfactant having an HLB value of less that about 10 (claim 1). Patel et al. teaches a hydrophobic therapeutic agent is rosiglitazone, which is the compound claimed (column 22, line 53). Patel et al. also teaches preparation of a formulation of a hydrophilic surfactant and a hydrophobic surfactant by heating and adding a therapeutic agent (columns 31 and 32, example 1). Patel et al. discloses the surfactant is a mixture of a reaction of a polyethylene glycol and a hydrogenated vegetable oil where the product results from transesterification (column 51, claims 26-28). Patel et al. also discloses the use of a macrogol glyceride (table 5). It is well known in the art that hydrogenated palm oil as claimed is a hydrogenated vegetable oil.

Patel et al. does not explicitly disclose an oral dosage form in a tablet form or the use of said dosage form for the treatment and/or prophylaxis of diabetes mellitus.

Hindley et al. teaches the use of 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione for the treatment of diabetes in a human or non-human, which is the same compound as claimed (column 40, claim 1). Hindley et al. also teaches the composition for oral administration in the form of tablets or capsules (column 10, lines 14 and 15).

It would have been prima facie obvious to one skilled in the art at the time of the invention, to use the composition formulation as taught by Patel et al. with the use of the compound as taught by Hindley et al. to treat diabetes mellitus. . It would have been prima facie obvious to use a stable polymorph of the macrogol glceride. Patel et al. teaches a hydrophobic therapeutic agent is rosiglitazone, which is the compound claimed (column 22, line 53) Hindley et al. teaches the use of 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione for the treatment of diabetes in a human or non-human, which is the same compound as claimed (column 40, claim 1).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 730am-500pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867 or Cecilia Tsang on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JANET L ANDRES/
Supervisory Patent Examiner, Art Unit 4131

/NANNETTE HOLLOMAN/
Examiner, Art Unit 4131